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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314
27752	7590	06/03/2004	EXAMINER	
THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL TECHNICAL CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 06/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/692,634	Applicant(s) RENNIE ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 20-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 20-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/25/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response filed on September 25, 2003 has been entered. Claims 1-9, 20-30 are pending and are under consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangadharan et al US Patent 5,643,582 in view of Szentmiklosi US Patent 5,244,880 and Davidson et al US Patent 6,080,783.

Applicant's arguments filed September 25, 2003 have been fully considered but they are not persuasive.

As the initial matter and in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the claims are rejected based on the combined teachings of the references. All elements of the claims are described by the combined teachings of the references. Therefore, merely arguing that Gangadharan, Szentmiklosi or Davidson dose not teach nasal compositions comprising a pyroglutamic acid and an organic acid having a dissociation constant value of from about 3.0-5.0 is not persuasive, because their combined teachings provides for such limitations for the reasons set forth on record.

Second, Examiner would point out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Here, the instant use of the composition for nasal administration does not impart patentability over the cited references.

As argued in the previous Office Action at pages 4-5, the recitation of “nasal composition” does not involve any unobvious difference between the structure of the claimed composition and those of the cited references, because such limitations relates solely to the matter of use of the claimed composition. Accordingly, the manner or method in which such claimed compositions are to be utilized is not germane to the issue of patentability of the composition itself, because the structure provided by the combined teachings of the references possess the capabilities requisite to meet the terms and function of the instant claims. Therefore, the mere recitation of “nasal compositions” does not involve an unobvious difference between the compositions of the prior art and those instantly claimed.

Examiner points out that benzoic acid of Gangadharan is an organic acid with a pKa of 3.0 to about 5.0. In fact, the instant application acknowledges such fact (see instant specification, page 6, line 21, claim 5). Moreover, the functional limitation of “providing a surface pH of the nasal cavity tissue from about 3.5-5.5” does not impart patentability over the cited references, because the combined teachings of the

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references meet all the elemental components of the claimed invention, and therefore, its functional characteristics as well.

Furthermore, Applicant has not provided any reasoning as to why topical compositions of Szentmiklosi would not encompass nasal composition. As set forth in the previous Office Action Examiner views topical pharmaceutical compositions to encompass nasal compositions. Therefore, combining the teachings of Gangadharan Szentmiklosi and Donadlson would be proper as they are directed to topical modes of drug delivery. Thus, since all elements of the instant claims are taught in the cited references combining them for the reasons of record would have been *prima facie* obvious.

Claims 1-9, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangadharan et al US Patent 5,643,582 in view of Szentmiklosi US Patent 5,244,880, Davidson et al US Patent 6,080,783 and EP 301 772 B1 (EP '772).

The teachings of Gangadharan, Szentmiklosi and Davidson are described previously. Their combination fails to teach various organic acids that are enumerated in the instant claims 5 and 25.

EP '772 is merely used to show the state of art for using carboxylic acids of claims 5 and 25 such as citric acid, glutamic acid, succinic acid, malonic, glutaric, adipic or benzoic acids. Accordingly all such acids are routinely used in the art as absorption promoters for nasal administration. (see abstract, page 3, lines 30-34; page 10, lines 40-55).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Gangadharan's composition by substituting its pyroglutamic acid salts with pyroglutamic acid of Szentmiklosi, because they are art recognized functional equivalents. Further, the ordinary skill in the art would have been motivated to add zinc salts of Davidson to Gangadharan's composition because he would have had a reasonable expectation of success in improving its clinical benefits for nasal application. Finally, adding all such art equivalent carboxylic acids to enhance absorption of an active agent through nasal mucosa would have been well within purview of an ordinary artisan, because as set forth in EP '772 and employing such agents would improve absorption of the active nasal drug and thus enhance clinical efficacy of the composition.

Conclusion

No claims are allowed. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 25, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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